K122470

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PENTAX Medical Company
A Division of PENTAX of America, Inc.

510(K) Summary

APR 10 2013

The following summary is provided in accordance with 21 CFR 807.92:

Date: April 08, 2013

Sponsor Information:

PENTAX Medical Company,
A Division of PENTAX America, Inc.
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Montvale, New Jersey 07645-1782

Contact Person:

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Title:	Regulatory Manager
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Manufacturer:

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-Cho
Nagai-Shi, Japan, 993-0012

FDA Establishment Registration #3003782606

Identification of the Proposed Device:

Proprietary/Trade Name:	PENTAX EPK-i5010 Video Processor
Common/Usual Name:	Endoscopic Video Processor and Light Source
Classification Name:	Endoscopic video imaging system/component, gastroenterology-urology
Regulation Number:	21 CFR Part 876.1500
Regulation Description:	Endoscope and accessories
Medical Specialty:	Gastroenterology/Urology
Regulatory Class:	Class II
Product Code:	FET and GCT

Device Description:

The PENTAX EPK-i5010 video processor consists of a video system, integrated light source, monitor, and ancillary equipment. This processor is intended for endoscopic diagnostic, treatment and video observation. It is intended to process electrical signals from a video endoscope.

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The PENTAX EPK-i5010 offers an optional digital, post-processing imaging enhancement technology called the PENTAX *i*-Scan™ modes 1, 2, and 3, which is intended to give the user an enhanced view of the texture of the mucosal surface and blood vessels. *i*-Scan 1 provides the user with a view that sharpens surface vessels and enhances surface texture of the mucosa. *i*-Scan 2 provides the user with increased visibility of blood vessels while also providing the same enhancements to the mucosa achieved in *i*-Scan 1. *i*-Scan 3 provides the user with increased visibility of blood vessels including dimly illuminated far-field regions while also providing the same enhancement to the mucosa achieved in *i*-Scan 1. The user can select either white light image or *i*-Scan modes by pressing a pre-programmed button on the scope, by using a pre-programmed foot pedal or by pressing a keyboard button. *i*-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling.

The EPK-i5010 video processor incorporates the hardware of the EPK-i5020 video processor model (K 113873) and the PENTAX *i*-Scan™ technology.

The EPKi-5010 is compatible with PENTAX flexible and rigid k-Series and i-Series videoscopes. The subject premarket notification is specific for gastrointestinal videoscopes and colonovideoscopes.

PENTAX Medical Company considers video endoscope families, defined as a grouping of endoscopes with the same: Intended diagnostic/ therapeutic affect for given anatomy (with respect to the indication for procedure), method(s) of introduction (trans oral, trans rectal, etc), Technical characteristics (design, materials, etc), and range of descriptive characteristics (specifications). Changes within the families are considered not-significant changes and mechanics for the description and grouping of endoscope families include 510(k) consideration for changes.

Intended Use:
The PENTAX EPK-i5010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal endoscopic diagnosis, treatment and video observation.

The PENTAX EPK-i5010 includes PENTAX *i*-Scan™, a digital, post-processing imaging enhancement technology. *i*-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. *i*-Scan is compatible with PENTAX k-series and i-series gastrointestinal videoscopes and colonovideoscopes.

Technology Characteristics:
The EPK-i5010 Video Processor has the same fundamental scientific technology as commercially available endoscope video processor and the substantially equivalent predicate devices.

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Substantial Equivalence Determination:

1. **Summary of Nonclinical Tests**
   The PENTAX EPK-i5010 Video Processor complies with voluntary standards as detailed in this premarket notification submission. The following quality assurance measures were applied to the design and development:

   - Animal Model Testing
   - Image Enhancement Analysis
   - Endoscope Optical Testing
   - Risk Management (Analysis & Mitigation)
   - Requirements Reviews
   - Design Reviews
   - Unit Testing (Software & Hardware Verification)
   - Integration testing (Software & Hardware Verification)
   - Performance testing (Software & Hardware Verification)
   - Safety testing (System level Verification & Validation)
   - Simulated use testing (System level QA Validation)
   - Electrical testing according to IEC 60601
   - Software validation performed in accordance with IEC 62304

2. **Summary of Clinical Tests**
   A total of seven (7) clinical studies are presented in this review to help establish the safety of the device. The studies were conducted in Germany (3), Japan (1) and Korea (3). An overall total of 975 patients were evaluated in the 7 clinical studies. All of the 7 studies used the PENTAX EPK-i processor with *i*-Scan technology.

   Four of the studies were conducted on the esophagus totaling 350 patients and three of the studies were conducted on the colon, totaling 625 patients.
   It should be noted that out of the 975 patients in the seven (7) clinical studies conducted with the PENTAX EPK-i video processor there were no safety issues reported.

3. **Predicate Device:**
   PENTAX EPK-i5010 Video Processor is substantially equivalent to the following devices:

Legally Marketed Device(s)	510(k) #
EVIS EXERA III VIDEO SYSTEM	K112680
PENTAX EPK-i5020 Video Processor	K113873

The subject device is also substantially equivalent to other legally marketed video processors for use with endoscopes including, but not limited to the Olympus predicate K100584. The EPK-i5010 video processor incorporates the hardware of the EPK-i5020 video processor model and the optional *i*-Scan™ technology. All other functions and specifications between the two processors are substantially identical.

The similarities and differences between the Olympus EVIS EXERA II and III Video System and the PENTAX EPK-i5010 Video Processor can be seen in the Table 1.

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When compared to the predicate devices, the EPK-i5010 does not incorporate any significant changes in the Intended Use, in the Method of Operation, Material or Design that could be considered to affect the safety or effectiveness of the Medical Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 22, 2013

PENTAX of America, Inc.
PENTAX Medical Company
% Robert Schiff, Ph.D., RAC, CQA, FRAPS
President
Schiff & Company, Inc.
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

Re: K122470
Trade/Device Name: PENTAX EPK-i5010 Video Processor
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: PEA
Dated: March 6, 2013
Received: March 7, 2013

Dear Dr. Schiff:

This letter corrects our substantially equivalent letter of April 10, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122470

Device Name: PENTAX EPK-i5010 Video Processor

Indications for Use:

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The PENTAX EPK-i5010 includes PENTAX i-Scan™, a digital, post-processing imaging enhancement technology. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan is compatible with PENTAX k-series and i-series gastrointestinal videoscopes and colonovideoscopes.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122470